



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 12 2007

Food and Drug Administration
Rockville MD 20857

Re: Nexium
Docket No. 2001E-0365

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
• Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the patent term extension application for U.S. Patent No. 4,738,974 filed by AstraZeneca, LP, under 35 U.S.C. § 156. The patent claims Nexium (esomeprazole magnesium), new drug application (NDA) 21-153.

In the February 28, 2002, issue of the Federal Register (67 Fed. Reg. 9299), the Food and Drug Administration (FDA) published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before August 27, 2002, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired. FDA received one due diligence petition during the comment period. However, that petition has been withdrawn from consideration as confirmed by a telephone conversation, January 3, 2007, between Brian Pendleton, FDA, and Bruce D. Radin, Esq., Budd Lerner, P.C. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Leslie Morioka
White & Case
Patent Department
1155 Avenue of the Americas
New York, NY 10036-2787